Over the years, there have been periodic inquiries about reviving the marketing order, but no formal requests for reactivation have ever materialized. In any case, with the passage of time and changes in industry structure and operating practices since the order was formulated, a much revised marketing order would have to be established. The need for a new marketing order would have to be justified and supported by a large majority of current Maine potato producers. This would require a public hearing and a producer referendum. Thus, there is little justification to continue the current marketing order.

We believe that conducting a termination referendum would merely reaffirm the Maine potato industry's continued lack of interest in a marketing order and that conducting such a referendum would be wasteful of Departmental and public resources.

Therefore, pursuant to section 608c(16)(A) of the Act and § 950.84 of the order, the Department is considering the termination of Marketing Order No. 950, covering Irish potatoes grown in Maine. If the Secretary decides to terminate the order, trustees would not need to be appointed to continue in the capacity of concluding and liquidating the affairs of the former committee, since no funds or property remain to be distributed or liquidated.

Section 608c(16)(A) of the Act requires the Secretary to notify Congress 60 days in advance of the termination of a Federal marketing order. Congress will be so notified upon publication of this proposed rule.

Based on the foregoing, the Administrator of the AMS has determined that this action would not have a significant impact on a substantial number of small entities.

A 30-day comment period is provided to allow interested persons to respond to this proposal. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 950

Marketing agreements, Reporting and recordkeeping requirements, Potatoes.

## PART 950—[REMOVED]

For the reasons set forth in the preamble, and under the authority of 7 U.S.C. 601–674, 7 CFR part 950 is proposed to be removed.

Dated: November 9, 1995.

Kenneth C. Clayton,

*Acting Administrator.*

[FR Doc. 95–28324 Filed 11–15–95; 8:45 am]

BILLING CODE 3410–02–P

## Animal and Plant Health Inspection Service

## 9 CFR Part 113

**[Docket No. 95–012–1]**

## Viruses, Serums, Toxins, and Analogous Products; Rabies Vaccine, Killed Virus and Rabies Vaccine, Live Virus

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to amend the standard requirements for establishing the immunogenicity of Rabies Vaccine, Killed Virus and Rabies Vaccine, Live Virus. The amendment would change and clarify alternate test procedures which may be used in animals other than carnivores. Under the proposed rule, when a reduced number of challenge animals is used in a rabies immunogenicity test, all vaccinates must survive challenge. If one or more of the challenged vaccinates die of rabies, all of the remainder of the vaccinates would have to be challenged or the test would be deemed unsatisfactory and terminated.

This proposed action would correct a problem associated with rabies immunogenicity tests in the regulations and make other changes deemed necessary for clarity and consistency.

**DATES:** Consideration will be given only to comments received on or before January 16, 1996.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 95–012–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 95–012–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead (202) 690–2817 to facilitate entry into the comment reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, USDA, 4700 River Road Unit 148, Riverdale, MD 20737–1237, (301) 734–8245.

**SUPPLEMENTARY INFORMATION:**

Background

The regulations in 9 CFR part 113 pertain to standard requirements for the preparation of veterinary biological products. A standard requirement consists of test methods, procedures, and criteria established by the Animal and Plant Health Inspection Service to determine that a veterinary biological product is pure, safe, potent, and efficacious and not worthless, dangerous, contaminated, or harmful.

The standard requirements for Rabies Vaccine, Killed Virus, and for Rabies Vaccine, Live Virus, appear in §§ 113.209 and 113.312, respectively. Sections 113.209(b)(4) and 113.312(b)(4) provide for an alternative immunogenicity test, for domestic species other than dogs and cats, that reduces the number of animals that must be challenged to a minimum of five vaccinates and five unvaccinated control animals. The regulations require that a minimum of 25 animals be vaccinated and blood be taken for serology at prescribed intervals postvaccination. All surviving test animals must be challenged 1 year after vaccination unless the alternative test is used. In the case of the alternative test for domestic species other than dogs or cats, the five vaccinates with the lowest rabies antibody titers at each of the last two bleedings, and all vaccinates with titers below 1:10, as determined by the mouse serum neutralization (SN) test or below 1:16 by the rapid-fluorescent-focus-inhibition test at any bleeding, must be challenged at 1 year after vaccination.

The following example illustrates how the current regulations can lead to different interpretations for the rabies immunogenicity test for species other than dogs and cats. The regulations in §§ 113.209(b)(3)(v) and 113.312(b)(3)(v) (applicable to all animal species) require that the statistical equivalent of 22 out of 25 or 26 out of 30 vaccinates remain well for 90 days after challenge. If only five vaccinates are challenged and three die of rabies, the test would be deemed unsatisfactory under §§ 113.209(b)(3)(v) and 113.312(b)(3)(v). The results would be considered unsatisfactory because survival of 2 of 5 animals is not statistically equivalent to survival of 22 of 25 or 26 of 30 animals.

Sections 113.209(b)(4) and 113.312(b)(4) (which apply to animals other than dogs and cats), however, state that all unchallenged vaccinates shall be considered protected for purposes of the test when evaluated for acceptance. The previous test would be considered satisfactory under §§ 113.209(b)(4) and 113.312(b)(4), since the unchallenged vaccinates would be deemed protected, meeting the requirement that 22 of the 25 vaccinates be protected for a satisfactory test. For this reason, the

regulations in §§ 113.209(b)(4) and 113.312(b)(4) need to be amended.

Sections 113.209(b)(4) and 113.312(b)(4) also need to be amended because serologic titer is not sufficiently correlated with efficacy to ensure that all of the unchallenged vaccinates in a reduced immunogenicity test would be protected after a real challenge.

The amendment would clarify which of the vaccinates should be challenged under §§ 113.209(b)(4) and 113.312(b)(4), and would require that all challenged vaccinates remain well for 90 days in order for the test to be satisfactory. The amendment would specify that the reduced immunogenicity test described in §§ 113.209(b)(4) and 113.312(b)(4) may not be used for carnivores (e.g., dogs, cats, and ferrets). The amendment would therefore exclude from a reduced challenge test species of animals that have a high potential for transmitting rabies.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This proposed rule amending §§ 113.209 and 113.312 is necessary to clarify the regulations regarding the rabies immunogenicity test. The amendment would clarify which animals are to be challenged in a reduced immunogenicity study and the procedures to follow when one or more of the vaccinates die of rabies. The proposed amendment would require that additional vaccinates be challenged if one of the low titer vaccinates succumbs to rabies. In 7 of the last 10 rabies challenge tests of non-carnivores, firms elected to challenge 25 or more animals. In the remaining three cases in which a reduced number of animals were challenged in accordance with current § 113.209 or § 113.312, paragraph (b)(4), no additional animals were challenged and no additional animals would have been challenged under the proposed rule. The proposed amendment, therefore, would have minimal economic effect.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or record keeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 113 would be amended as follows:

## PART 113—STANDARD REQUIREMENTS

1. The authority citation for part 113 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

2. Section 113.209 would be amended by revising paragraph (b)(4) to read as follows:

**§ 113.209 Rabies Vaccine, Killed Virus.**

* * * * *

(b) * * *

(4) An alternative to challenging all surviving test animals in accordance with paragraph (b)(3)(iv) of this section may be used when the test animals are of species other than carnivores. Vaccinates shall be challenged at 1 year postvaccination. These shall include five vaccinates with the lowest SN titers at the 270th-day bleeding, five vaccinates with the lowest SN titers at the 365th-day bleeding, and all vaccinates with SN titers below 1:10 by the mouse SN test or below 1:16 by the rapid-fluorescent-focus-inhibition test at any bleeding. At least five SN-negative controls of each species shall be challenged at the same time as the vaccinates. All SN titers shall be titrated to an endpoint. All of the challenged vaccinates must remain well for a period of 90 days, and at least 80 percent of the controls must die of rabies for a satisfactory test without further challenge. If one or more of the vaccinates die from rabies, all the remaining vaccinates, regardless of titer, along with the five controls shall be challenged. The cumulative results from the two challenges shall be evaluated for acceptance as specified in paragraph (b)(3)(v) of this section.

3. Section 113.312 would be amended by revising the section heading and paragraph (b)(4) to read as follows:

**§ 113.312 Rabies Vaccine, Live Virus.**

* * * * *

(b) * * *

(4) An alternative to challenging all surviving test animals in accordance with paragraph (b)(3)(iv) of this section may be used when the test animals are of species other than carnivores. Vaccinates shall be challenged at 1 year postvaccination. These shall include five vaccinates with the lowest SN titers at the 270th-day bleeding, five vaccinates with the lowest SN titers at the 365th-day bleeding, and all vaccinates with SN titers below 1:10 by the mouse SN test or below 1:16 by the rapid-fluorescent-focus-inhibition test at any bleeding. At least five SN-negative controls of each species shall be challenged at the same time as the vaccinates. All SN titers shall be titrated to an endpoint. All of the challenged vaccinates must remain well for a period of 90 days, and at least 80 percent of the controls must die of rabies for a satisfactory test without further challenge. If one or more of the vaccinates die from rabies, all the remaining vaccinates, regardless of titer, along with the five controls shall be challenged. The cumulative results from the two challenges shall be evaluated for acceptance as specified in paragraph (b)(3)(v) of this section.

* * * * *

Done in Washington, DC, this 8th day of November 1995.

Terry L. Medley,

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 95–28325 Filed 11–15–95; 8:45 am]

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